K002043

MAY 21 2001

510(k) Summary

From: Christoph Weismayer
Purdue Technology Park
Continence Therapies Inc.
Suite D1-113
3000 Kent Avenue
West Lafayette, IN 47906
Fax: 765-775-2110
Tel: 765-494-5922

Regarding:

- Trade name – pelvex hometrainer
- Common name - perineometer
- Classification number - 884.1425

To whom ever it may concern:

Continence therapies Inc. would like to apply to the FDA to review if the pelvex hometrainer is substantially equivalent to the PMTx by Peritron (884.1425) an the InCare system by Hollister (884.1425).

The device is (similar to Peritron) a device which can help women to exercise their pelvic floor muscle, a muscle responsible for stress incontinence and sexual dysfunctioning. It consists of a pressure sensitive sensor which is introduced into the vagina like a tampon. The device women then to observe pelvic floor activity on a biofeedback display and learn how to contract the pelvic floor muscle correctly.

The major difference to the PMTx is that the pressure in the sensor can be increased slightly to make the exercise more difficult. Similarily to the InCare system the device is battery powered and has an LCD display. The pressure in the sensor is measured via a piezo element in the biofeedback unit and then displayed on the screen

Summary table of similarities and differences

feature	The PMTx	The InCare System	The pelvex hometrainer
Main indication for use	Stress incontinence and sexual health – preventive use	Stress incontinence and sexual health – preventive use	Stress incontinence and sexual health – preventive use
Use	Air filled sensor is introduced into the vagina	Pressure sensitive sensor is introduced into the vagina	Air filled sensor is introduced into the vagina
Session length	Labeling recommends no longer than 30 minutes, but increases with improvement	Labeling recommends no longer than 30	Labeling recommends two sessions for 10 minutes
Sensitivity levels	1 level circa 50mm/hg	3 levels: 0-25mm/hg 0-50mm/hg 0-100mm/hg	Individually adjustable (only up to ~200mm/hg)
Display	Mechanical display	Computer display	LDC - display
Pressure in Sensor	Not changeable	Not changeable	changeable
Power source	mechanical	batteries	batteries
Sensor	One piece, non disposable but washable, latex	No structural integrity	One piece, disposable, washable, silicone
Intended setting	At home	Physician office and home use	At home
Tone to signal successful contraction?	No, only visual display	Yes	Yes
Hygiene	Washing of device	Washing of device	Washing of device or condom
Sensor	One piece, non disposable but washable, latex	No structural integrity	One piece, disposable, washable, silicone
Intended setting	At home	Physician office and home use	At home
Tone to signal successful contraction?	No, only visual display	No, only computer screen display	Yes
Hygiene	Washing of device	Washing of device	Washing of device or condom

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2001

Mr. Christoph Weismayer
Continence Therapies, Inc.
Purdue Technology Park
Suite D1-113
3000 Kent Avenue
WEST LAFAYETTE IN 47906

Re: K002043
Pelvex Hometrainer
Dated: February 12, 2001
Received: February 20, 2001
Regulatory Class: II
21 CFR §884.1425/Procode: 85 HIR

Dear Mr. Weismayer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002043

Device Name: Pelvex Hometrainer

Indications For Use:

The pelvex hometrainer is intended to assist women in performing Kegel exercises, which may help in the treatment of urinary incontinence.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002043

Prescription Use ✓
(Per 21 CFR 801.109)